

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: ROSUVASTATIN CALCIUM : MDL No. 08-1949-JJF
PATENT LITIGATION, :
:

ASTRAZENECA PHARMACEUTICALS :
LP, ASTRAZENECA UK LIMITED, :
IPR PHARMACEUTICALS INC., AND :
SHIONOGI SEIYAKU KABUSHIKI :
KAISHA, :
: Plaintiffs, :
: v. : Civil Action No. 07-805-JJF-LPS
: :
MYLAN PHARMACEUTICALS INC., :
: Defendant. :
:

ASTRAZENECA PHARMACEUTICALS :
LP, ASTRAZENECA UK LIMITED, :
IPR PHARMACEUTICALS INC., AND :
SHIONOGI SEIYAKU KABUSHIKI :
KAISHA, :
: Plaintiffs, :
: v. : Civil Action No. 07-806-JJF-LPS
: :
SUN PHARMACEUTICAL INDUSTRIES :
LTD., et al., :
: Defendants. :
:

ASTRAZENECA PHARMACEUTICALS :
LP, ASTRAZENECA UK LIMITED, :
IPR PHARMACEUTICALS INC., AND :
SHIONOGI SEIYAKU KABUSHIKI :
KAISHA, :
: Plaintiffs, :
: v. : Civil Action No. 07-807-JJF-LPS
: :
SANDOZ INC., :
: Defendant. :
:

ASTRAZENECA PHARMACEUTICALS :
LP, ASTRAZENECA UK LIMITED, :
IPR PHARMACEUTICALS INC., AND :
SHIONOGI SEIYAKU KABUSHIKI :
KAISHA, :
: Plaintiffs, :
: v. : Civil Action No. 07-808-JJF-LPS
: :
PAR PHARMACEUTICALS INC., :
: :
Defendant. :
: _____
ASTRAZENECA PHARMACEUTICALS :
LP, ASTRAZENECA UK LIMITED, :
IPR PHARMACEUTICALS INC., AND :
SHIONOGI SEIYAKU KABUSHIKI :
KAISHA, :
: Plaintiffs, :
: v. : Civil Action No. 07-809-JJF-LPS
: :
APOTEX INC. AND APOTEX CORP., :
: :
Defendants. :
: _____
ASTRAZENECA PHARMACEUTICALS :
LP, ASTRAZENECA UK LIMITED, :
IPR PHARMACEUTICALS INC., AND :
SHIONOGI SEIYAKU KABUSHIKI :
KAISHA, :
: Plaintiffs, :
: v. : Civil Action No. 07-810-JJF-LPS
: :
AUROBINDO PHARMA LTD. AND :
AUROBINDO PHARMA USA INC., :
: :
Defendants. :
: _____
ASTRAZENECA PHARMACEUTICALS :
LP, ASTRAZENECA UK LIMITED, :
IPR PHARMACEUTICALS INC., AND :
SHIONOGI SEIYAKU KABUSHIKI :
KAISHA, :
: Plaintiffs,

v. : Civil Action No. 07-811-JJF-LPS
:
COBALT PHARMACEUTICALS INC. :
AND COBALT LABORATORIES INC., :
:
Defendants. :
:
ASTRAZENECA PHARMACEUTICALS :
LP, ASTRAZENECA UK LIMITED, :
IPR PHARMACEUTICALS INC., AND :
SHIONOGI SEIYAKU KABUSHIKI :
KAISHA, :
:
Plaintiffs, :
:
v. : Civil Action No. 08-359-JJF-LPS
:
AUROBINDO PHARMA LTD. AND :
AUROBINDO PHARMA USA INC., :
:
Defendants. :
:
ASTRAZENECA PHARMACEUTICALS :
LP, ASTRAZENECA UK LIMITED, :
IPR PHARMACEUTICALS INC., AND :
SHIONOGI SEIYAKU KABUSHIKI :
KAISHA, :
:
Plaintiffs, :
:
v. : Civil Action No. 08-426-JJF-LPS
:
TEVA PHARMACEUTICALS USA, :
:
Defendant. :
:

MEMORANDUM ORDER

Pending before the Court is an Objection (D.I. 142 in Civ. Act. No. 07-805-JJF) filed by Defendant, Mylan Pharmaceuticals, Inc. ("Mylan") and an Objection (D.I. 146 in Civ. Act. No. 07-806-JJF and D.I. 142 in Civ. Act. No. 07-808-JJF) filed by Defendant, Par Pharmaceutical, Inc. ("Par") to the Magistrate

Judge's Report And Recommendation Regarding Claim Construction (D.I. 136 (sealed version), 137 (redacted version) in Civ. Act. No. 07-805; D.I. 141 (sealed version), 142 (redacted version) in Civ. Act. No. 07-806; D.I. 144 (sealed version), 145 (redacted version) in Civ. Act. No. 07-807; D.I. 135 (sealed version), 136 (redacted version) in Civ. Act. No. 07-808; D.I. 161 (sealed version), 162 (redacted version) in Civ. Act. No. 07-809; D.I. 187 (sealed version), 188 (redacted version) in Civ. Act. No. 07-810; D.I. 151 (sealed version), 152 (redacted version) in Civ. Act. No. 07-811; D.I. 121 (sealed version), 122 (redacted version) in Civ. Act. No. 08-359; D.I. 121 (sealed version), 122 (redacted version) in Civ. Act. No. 08-426; D.I. 190 (sealed version), 191 (redacted version) in MDL No. 08-1949).¹ For the reasons discussed, the Court will overrule the Objections and adopt the Report and Recommendation in all of the cases in which it was filed.

I. STANDARD OF REVIEW

Pursuant to 28 U.S.C. § 636(b)(1)(B) and Fed. R. Civ. P. 72(b)(3), the Court may accept, reject, or modify the recommendations of the magistrate judge. The court may also receive further evidence or return the matter to the magistrate judge with instructions for proceeding. Id.

¹ The Court notes that Objections were only filed in Civil Action Nos. 07-805-JJF; 07-806-JJF and 07-808-JJF.

In this case, the parties agree that the claim construction is dispositive of the defense of non-infringement raised by Mylan and Par. Accordingly, the Court will conduct a de novo review of Magistrate Judge Stark's claim construction.

II. DISCUSSION

By its Objection, Mylan contends that Magistrate Judge Stark erred in adopting Plaintiffs' proposed claim construction over Defendants' proposed claim construction regarding the disputed terms contained in claim 6 and claim 8 of U.S. Reissue Patent RE37,314 (the "'314 patent"), which stemmed from U.S. Patent No. 5,260,440 (the "'440 patent) owned by Shionogi Seiyaku Kabushiki Kaisha ("Shionogi"). Specifically, Mylan contends that Magistrate Judge Stark erroneously concluded that (1) claim 6 of the '314 patent should be read as a "unitary term" that does not require construction of each component of the term, and (2) claims 6 and 8 of the '314 patent exclude "monocalcium bis" salts.

Par has joined in Mylan's Objection to the extent it challenges Magistrate Judge Stark's conclusions regarding the parties' arguments concerning prosecution disclaimer of "monocalcium bis" salts. Par does not join in Mylan's argument concerning unitary construction of claim 6.

A. Whether Claim 6 Of The '314 Patent Should Be Read As A Unitary Term

Claim 6 of the '314 patent provides:

6. The compound 7-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methyl-methylsulfonylamino)pyrimidin-5-yl)-(3R, 5S)-dihydroxy-(E)-6-heptenoic acid in the form of a non-toxic pharmaceutically acceptable salt thereof.

In construing this term, Judge Stark took a unitary approach to the claim and recommended that claim 6 be construed as:

A non-toxic pharmaceutically acceptable salt of the compound 7-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methyl-N-methylsulfonylamino)pyrimidin-5-yl)-(3R, 5S)-dihydroxy-(E)-6-heptenoic acid.

In objecting to this claim construction, Mylan contends that the Federal Circuit has never applied a "unitary" approach to claim construction and that the application of such an approach here results in rewriting the claims to delete from them the words "in the form of" and "thereof." Mylan contends that the failure to construe each component of the claim, namely the terms "acid," "salt," "in the form of" and "thereof," impermissibly broadens the claim to embrace a larger set of compounds.

According to Mylan, this larger set of compounds was not considered part of the '314 patent during the reissue proceedings, and Shionogi, who requested the reissue, abandoned these broader claims such that claim 6 should be limited to the much narrower set of compounds that are an ". . . acid in the form of a . . . salt thereof." (D.I. 142 in Civ. Act. No. 07-

805-JJF at 7-8).

In response, Plaintiffs contend that the words of claim 6 parceled out by Mylan are akin to phrases, and therefore, the word-by-word construction proposed by Mylan will depart from the context of the invention. More specifically, Plaintiffs contend that there is no need to define the term "acid" separately from the rest of the claim, because the term "acid" is used only as part of the definition of the compound which is claimed in the salt form. Plaintiffs further contend that under their proposed construction, as adopted by the Magistrate Judge, claim 6 is not broadened from the scope of the '440 patent, the original patent from which the '314 patent was reissued.

Reviewing the claim language, specification and prosecution history related to the disputed claim, the Court adopts the claim construction proposed by Judge Stark. The Federal Circuit has cautioned against a word-by-word approach to claim construction when such an approach to construction divorces itself from the context of the invention. See e.g., On Demand Machine Corp. v. Ingram Industries, Inc., 442 F.3d 1331, 1344 (Fed. Cir. 2006). In this case, the plain language of the disputed claim recites a heptenoic acid in salt form. This construction is consistent with the specification which provides eight examples disclosing a heptenoic acid in salt form. In this context, the Court agrees with Judge Stark that the term "acid" does not require an

individualized claim construction because it is part of the compound named in the claim. The Court's conclusion is further supported by the prosecution history of the '314 patent, which demonstrates that once Shionogi took measures to draft the acid out of the claim, by limiting the claim to the "acid in the form of a salt," the PTO allowed the claim. From this context, it is evident that the PTO and Shionogi viewed the acid of the claimed compound to be different from the salt of the claimed compound.

Mylan contends that use of the phrase "in the form of" renders the claim ambiguous, but the Court disagrees in light of the prosecution history. It is evident that the "in the form of" language was derived from back and forth discussions between Shionogi and the PTO to yield the agreed upon result that Shionogi claim the pharmaceutically acceptable salt of the acid recited in the claim 6 compound and remove from the scope of the claim the acid itself. (D.I. 52 in MDL NO. 08-1949, Exh. 4 at AZ00411430.) It is further evident from the prosecution history, that the PTO did not view this amendment to the '314 reissued patent to broaden the scope of the claim beyond the original '440 patent. (Id.)

The Court agrees with Judge Stark that Mylan's proposed claim construction impermissibly reads into the claim a process that was not recited by the patentee. As Judge Stark explained, such a construction would exclude one of the preferred

embodiments which describes a different process of forming the calcium salt of the claimed compound. '314 patent, col. 13, l. 59-col. 14, l.8 (describing rosuvastatin calcium salt as being formed from the sodium salt of rosuvastatin, and not from the heptenoic acid). As the Federal Circuit has noted, a claim construction which excludes a preferred embodiment is rarely the correct construction. See, e.g., Hoechst Celanese Corp. v. BP Chemicals Ltd., 78 F.3d 1575, 1581 (Fed. Cir. 1996) ("[I]t is unlikely that an inventor would define the invention in a way that excluded the preferred embodiment, or that persons of skill in this field would read the specification in such a way.")

In sum, the Court agrees with and will adopt the proposed construction of Judge Stark for claim 5 of the '314 patent, as well as the rationale provided by Judge Stark in making his recommendation. Accordingly, the Court will overrule Mylan's Objection as it pertains to claim 6 of the '314 patent.

B. Whether Shionogi Disclaimed "Monocalcium Bis"
During The Reissue Proceedings

Claim 8 of the '314 patent is a dependent claim which reads:

8. The compound of claim 6 in the form of a calcium salt.

Judge Stark construed claim 8, consistent with its plain language to be "[t]he compound of [c]laim 6 in the form of a calcium salt." In rendering this construction, Judge Stark concluded that Shionogi did not disclaim "monocalcium bis."

In objecting to this claim construction, Mylan and Par contend that Shionogi disclaimed "monocalcium bis" by amendment during the reissue proceedings. In this regard, Mylan and Par contend that "monocalcium bis" was outside the scope of the original patent, and that Shionogi disavowed coverage of a "monocalcium bis" when he deleted all references to the compound after the examiner's rejection of it. Mylan and Par further contend that the examiner concluded that the '440 patent was "limited to salt cations with a +1 charge." (D.I. 142 in Civ. Act. No. 07-805-JJF at 20.)

In response, Plaintiffs contend that Shionogi did not disclaim "monocalcium bis" salt in the prosecution history. According to Plaintiffs, Shionogi rewrote claim 8 to make it dependent on claim 6, with the intent that the two claims be identical in scope. In this regard, Plaintiffs contend that Shionogi made it clear that the claimed calcium salt had a calcium cation charge of +2, and thus, would necessarily form a salt with two rosuvastatin (-1) anions. Plaintiffs contend that this compound is, by definition, a "bis" salt. Plaintiffs point out that the examiner's attempt to limit the original '440 patent to +1 cations was overruled by his PTO supervisors.

Reviewing the claim language, specification and prosecution history related to the disputed claim, the Court adopts the claim construction proposed by Judge Stark and agrees with his

conclusion that Shionogi did not disclaim "monocalcium bis" during the reissue proceedings. "[A] patentee may limit the meaning of a claim term by making a clear and unmistakable disavowal of scope during prosecution." Computer Docking Station Corp. v. Dell, Inc., 519 F.3d 1366, 1374 (Fed. Cir. 2008) (quoting Purdue Pharma L.P. v. Endo Pharm., Inc., 438 F.3d 1123, 1136 (Fed. Cir. 2006)). As Judge Stark correctly noted, the record in this case does not contain an express disavowal of "monocalcium bis."

Mylan and Par attempt to infer a disavowal from Shionogi's decision to remove the term "monocalcium bis" from the claims. While it is true that Shionogi made this deletion, the Court cannot conclude that this constitutes a clear and unmistakable disavowal, where as here, the context of Shionogi's actions, taken as a whole, contradicts a disclaimer. As originally submitted, claim 8 was to read:

8. The compound monocalcium bis ((+)-7-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methyl-N-methylsulfonylamino)pyrimidin-5-yl)-(3R,5S)-dihydroxy-(E)-6-heptenoate).

(D.I. 52 in MDL No. 08-1949, Exh. 4 at AZ000411334.) Shionogi expressly equated this compound with the compound exemplified in Example 7 of the '314 patent. (Id. at AZ0004113340.) Claim 8 was rejected by the examiner, who then met with Shionogi. (Id. at AZ000411361.) The two agreed that "[b]is Claim 8 would be rewritten as a calcium salt." (Id. at AZ0004100375.) In

rewriting the claim to make it depend on claim 6, Shionogi stated that the revised claim 8 was "identical in scope" to the proposed Claim 8, only "now dependent on Claim 6 to clarify [its] relationship to the Claim 6 compound." (Id. at AZ000411378, AZ000411380.) That Shionogi did not substantively change claim 8 was evidenced by the examiner's continued rejection of the claim on the grounds that it fell outside the scope of the original '440 patent. More specifically, the examiner found that only +1 cation were covered by the original '440 patent (i.e. sodium, but not calcium). However, the examiner's view was overruled, and the proposed amendments were accepted by the PTO. (Id. at Exh. 4 at AZ00411430 and AZ00411495.) Further, as Judge Stark noted, a contrary construction would have excluded the exact preferred embodiment Shionogi meant to encompass in the originally submitted claim 8, a result which is illogical in light of the record, and in particular, Shionogi's views of the submitted claim.

In sum, the Court agrees with and adopts Judge Stark's interpretation of claim 8 of the '314, as well as the rationale advanced by him for this conclusion. Accordingly, the Court will overrule the Objections of Mylan and Par as they pertain to claim 8 of the '314 patent.

NOW THEREFORE, IT IS HEREBY ORDERED that:

1. The Objection (D.I. 142 in Civ. Act. No. 07-805-JJF) filed by Defendant, Mylan Pharmaceuticals, Inc. ("Mylan") is

OVERRULED.

2. The Objection (D.I. 146 in Civ. Act. No. 07-806-JJF and D.I. 142 in Civ. Act. No. 07-808-JJF) filed by Defendant, Par Pharmaceutical, Inc. is OVERRULED.

3. The Magistrate Judge's Report And Recommendation Regarding Claim Construction (D.I. 136 (sealed version), 137 (redacted version) in Civ. Act. No. 07-805; D.I. 141 (sealed version), 142 (redacted version) in Civ. Act. No. 07-806; D.I. 144 (sealed version), 145 (redacted version) in Civ. Act. No. 07-807; D.I. 135 (sealed version), 136 (redacted version) in Civ. Act. No. 07-808; D.I. 161 (sealed version), 162 (redacted version) in Civ. Act. No. 07-809; D.I. 187 (sealed version), 188 (redacted version) in Civ. Act. No. 07-810; D.I. 151 (sealed version), 152 (redacted version) in Civ. Act. No. 07-811; D.I. 121 (sealed version), 122 (redacted version) in Civ. Act. No. 08-359; D.I. 121 (sealed version), 122 (redacted version) in Civ. Act. No. 08-426; D.I. 190 (sealed version), 191 (redacted version) in MDL No. 08-1949) is ADOPTED.

October 20, 2009
DATE


UNITED STATES DISTRICT JUDGE